

## **Structured Product Labeling (SPL) OTC Sub-team Teleconference**

July 27, 2009, 1:00 – 2:00 pm ET

### **Call Summary**

#### **I. Call Attendees (based on emails received)**

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

- + Cheryl Blik, Teva Pharmaceuticals USA
- + Chris Guay, Procter and Gamble
- + Juris Lazdins, Novartis Consumer Health, Inc.
- + Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
- + Devon Morgan, Perrigo Company (sub-team co-leader)
- + Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
- + Janet Riffitts, McNeil Consumer Healthcare
- + Eva Rivera, Glemser Technologies Corporation
- + Howard Shatz, Data Conversion Laboratory, Inc.
- + Beth Thompson, Medline Industries, Inc.
- + Craig Trautman, Intagras
- + Ranga Velagaleti, BASF Corporation
- + JoAnn Witek, Consultant
- + Barbara Wolfe, Wyeth Consumer Healthcare
- + Marcia Howard, CHPA staff (sub-team liaison)

#### **II. Next Standing Teleconference:** August 24, 2009 (August 10<sup>th</sup> call **CANCELLED**)

#### **III. Discussion Topics**

##### **A. NLM Pillbox Initiative**

As there were no objections, David Hale (NLM) will be confirmed to participate on the August 24, 2009, SPL OTC sub-team. [Confirmed] Marcia Howard will send Hale the key questions and considerations outlined by sub-team members on the July 13<sup>th</sup> call. Those points are listed below.

- Confirm companies will submit samples of products to be photographed to NLM (or will they come from the companies).
- What is the source of the photos, *i.e.*, who provides the images?
- Who will be responsible for posting the images, and how would updates and changes be processed?
- If NLM produces the photos, what chain of custody and processes are/need to be in place to ensure accuracy of medication photographed (*i.e.*, how will NLM ensure that the accuracy of the sample is what is captured?)?

- What internal corporate resources, if any, will be needed to participate in the initiative?
- Will the Pillbox initiative replace the PDR or will there be two sources of information?
- As some companies also post images on their own websites, what is the potential impact, if any, on having the images posted at corporate websites as well as NLM?
- Would it be possible to link the image with SPL submissions?
- Will both sides of the medicine be photographed even imprints are only on one side?
- What happens if the shape of the tablet is copyrighted or trademarked?

Sub-team members should invite internal colleagues as necessary to participate on this call.

B. Posting OTC information to DailyMed/FDA Facts page

A short survey (yes/no/yes with caveats) will be sent to sub-team members to determine if there is a consensus position about whether or not OTC monograph drug listing information should be made available to the public via the NLM DailyMed website (or possibly the FDA Factspace currently under development). Once the survey results have been obtained, we will then be able to determine what comments, if any, can be sent to FDA for consideration on behalf of the sub-team.

**Survey Link:** Please respond by 5:00 pm ET on August 19, 2009

[http://www.surveymonkey.com/s.aspx?sm=HSJw4A\\_2bh1hwxMzvJv9H\\_2fdQ\\_3d\\_3d](http://www.surveymonkey.com/s.aspx?sm=HSJw4A_2bh1hwxMzvJv9H_2fdQ_3d_3d)

Companies are encouraged to provide their own feedback to FDA regardless of the decision of the sub-team. Although no timeframe was given, comments should be sent to the agency as soon as possible.

**IV. FDA Data Council Information** (*not all-inclusive*) – **NOTE: New Info Included**

- A. The FDA Data Standards Council's website was updated Sunday, July 12, 2009, to include updated terminology lists:

UNIs (now over 10,000 UNIs publically available) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>

Terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm>

- B. The FDA Data Standards Council's website was updated Thursday, July 16, 2009, to include new terms:

1. Business operation: API manufacture -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162527.htm>

2. Flavor: Marshmallow -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162541.htm>

- C. The FDA Data Standards Council's website was updated Thursday, July 16, 2009, to include updated terminology lists:

UNIIs -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>

Terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm>

- D. **Please only send SPL-related e-mails to the SPL e-mail account.** If you send a carbon copy of each of your SPL-related e-mails to [lonnie.smith@fda.hhs.gov](mailto:lonnie.smith@fda.hhs.gov) then Lonnie Smith (FDA) has to reach each message twice.

- E. The FDA Data Standards Council's website was updated Friday, July 24, 2009, to include updated terminology lists:

UNIIs -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm>

Terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm>

- F. Message received July 24, 2009, regarding common technical errors and other information.

Here is a list of common technical errors in SPL R4 documents received since the electronic drug establishment registration and drug listing pilot commenced on July 10, 2008, to June 1, 2009, when it became mandatory for the drug establishment registration and drug listing information to be provided in

Structured Product Labeling format (unless a waiver is granted), to the present date.

1. **Missing folder** - Place each SPL document and any associated image file(s) in a folder and upload the folder containing the SPL and image files via the FDA Gateway's "OC" directory.
2. **Incorrect or missing file extension** – The file extension for SPL documents is ".xml" and the file extension for image files is ".jpg".
3. **Incorrect file format** – Winzip (zipped files) Excel, PDF, Word, and eCTD files are not acceptable formats for documents submitted for the purpose of electronically registering a drug establishment, submitting or requesting a NDC labeler code, or listing a drug product via the FDA OC Gateway. Only XML and JPEG (jpg) file formats are acceptable.
4. **Submitting more than one XML file per folder** – Only one SPL file should be included in each folder.
5. **Incorrect SPL file name** – Use the SPL document ID with the file extension ".xml"
6. **Not using the suffix element** – Utilize the suffix element for any additional qualifiers (e.g. dosage form, route of administration, etc...) for proprietary names.

Additional notes:

1. SPL Technical Q&A training sessions are held each Monday (except Federal holidays) from 11:30 a.m. - 12:00 - p.m., (Eastern Time Zone): Audio Conference details: Telephone number: 1-866-775-9435 - Participant pass code: 2219058
2. Send SPL-related e-mails to the FDA SPL e-mail account: [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov). Do not send SPL-related e-mails to both [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov) and [lonnie.smith@fda.hhs.gov](mailto:lonnie.smith@fda.hhs.gov).
3. Test your SPL R4 documents via the Pragmatic Validator Lite tool to detect 90 - 95% of the technical errors which will be detected by FDA SPL R4 validation procedures:
4. The HL7 SPL Working Group has provided a hyperlink to the SPL Release Four Common Errors training slides: [http://spl-work-group.wikispaces.com/file/view/common\\_errors\\_spl\\_r4\\_training.pdf](http://spl-work-group.wikispaces.com/file/view/common_errors_spl_r4_training.pdf).

5. The HL7 SPL Working Group's OTC sub team has provided a hyperlink to an OTC SPL document template: <http://spl-work-group.wikispaces.com/OTC>.

G. Screenshot of the FDA Gateway screen that may be utilized as a guide for transmitting your Structured Product Labeling documents which are submitted for the purpose of requesting or providing your NDC labeler code, registering a drug establishment or listing a drug. [Provided as an attachment] - *New*

H. SPL R4 101 Training - Preparing Drug Establishment Registration and Drug Listing Submissions in SPL Format - *New*

Dates: **Mondays**, August 10, 2009 – December 28, 2009 (Except Federal Holidays)

Time: 10:00 – 11:00 a.m. (Eastern Time Zone)

Location: Web/Audio Conference

**Web conference details:**

Meeting Number: 747810891

Meeting Pass code: (This meeting does not require a password.)

Join Instructions for Instant Net Conference:

1. Go to <http://www.mymeetings.com/nc/>
2. Enter the required fields.
3. Indicate that you have read the Privacy Policy.
4. Click on "Proceed".

**Audio conference details:**

Telephone number: 1-866-775-9435

Participant pass code: 2219058

I. The FDA Data Standards Council SPL web page was updated on Thursday, July 30, 2009, to include a "SPL Starter Package." The hyperlink to the zip file containing the SPL starter package is located under the Resources heading on the SPL web page - *New*

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

J. PDF version of the presentation for "SPL R4 Training Module One - SPL Overview, NDC Labeler Code, Domestic & Foreign Establishment Registration." [Provided as attachment] – *New*

These slides replace modules one, two, three. These three modules have been combined into one two-hour training module.

The slides for the new SPL R4 training module two which replaced modules four, five, and six will be forwarded to you next week.

## V. Open Discussion by Sub-team Members

- There was a request to obtain clarification about the SPL OTC template to determine if the example represents how FDA would like for the submissions to be completed.

**Response:** The SPL OTC sample template was developed in conjunction with the CDER Office of Nonprescription Products (ONP). All submissions should follow the appropriate regulations.

- Guidance about how to handle questions from FDA import staff when drug listing for monograph OTC products was requested. In one instance, for example, a company was told the import staff did not have access to the necessary database to view/obtain the electronic submission data. Companies need to know how to proceed if and when this situation occurs, especially as it may delay importation of these products.

**Response:** FDA continues to education the reviewers and import staff about SPL submissions. During this period of transition, it was recommended that an email be sent to the Electronic Drug Registration and Listing staff ([edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)) when a product is expected to be imported to resolve any outstanding issues as quickly as possible.

- Companies were encouraged to participate in the weekly FDA Q&A sessions (see below for additional information).
  - One highlight from the July 27<sup>th</sup> call was that if a company is both a drug manufacturer and API manufacturer, both should be registered and both operations listed for the establishment in the SPL document.

## VI. Upcoming SPL Educational Forums

- A. FDA SPL R4 Training Sessions, including sessions on Repacked drug products, Combination products, Common errors in SPL R4 submissions, homeopathic drug products. See website for a complete listing.  
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

If you sign-up for a training session and do not receive confirmation at least 24 hours before the session begins, it is recommended that you contact Lonnie to confirm your registration.

Slides from the various training sessions that can be shared publicly are available at the SPL wiki page.

- B. FDA weekly SPL R4 Q&A/Training session  
June 8, 2009 – December 28, 2009  
Mondays (except Federal holidays; no session held on June 22<sup>nd</sup>)  
11:30 a.m. – 12:00 p.m. EST

Audio conference details:

Telephone number: 1-866-775-9435

Participant pass code: 2219058

- C. DIA SPL Workshop (August 11-12, 2009; The Westin Philadelphia, Philadelphia, PA)

<http://www.diahome.org/DIAHOME/Education/FindEducationalOffering.aspx?productID=20798&eventType=Meeting>

Early bird registration and discounted hotel rates expire July 31, 2009

MDH/07-30-09

SPL OTC Sub-team 27 July 2009 073009.doc  
Last Revised: July 31, 2009 Sent: July 31, 2009

REVISED OTC Product Listing to NLM DailyMed Website - Possible Pros and Cons  
NOT FOR CIRCULATION- From July 13<sup>th</sup> Discussion  
Revisions shown in blue

Key Issues:

- Should OTC product listing information submitted to FDA be made publicly available?
- If so, where should this information be listed to best ensure consumer access (e.g., NLM DailyMed, FDA website, other???)

Pros (listed randomly):

- Companies would be able to direct third party clients to website for information vs. having to respond to each individual request for information. **The website could also be beneficial when international organizations and authorities request information from an “FDA recognized” website.**
- Companies maintain control of data that is posted through their electronic submissions.
- FDA currently posting NDA & ANDA drug product listing so posting all OTC information would provide consistency.
- OTC products will be seen as “real” medicines that are treated like other human drug products, **i.e., gives validity to premise that OTCs are “real” drugs.**
- **Healthcare professionals should/could use website to determine drug interactions with other products.**
- Having the data publicly available will enhance search capabilities **for the agency, trade associations, and industry** for product ingredients especially when safety concerns arise.
- If the NLM Pillbox initiative is extended to OTC products, the posting information may be needed to coordinate the activity.
- **There is the possibility for enhances transparency – consumers would have access to the most current information and may encourage better compliance.**

Cons (listed randomly):

- Is there any concern that counterfeiters will use posted label information for illegal activities? **(During the call it was noted that counterfeiters can purchase the product to obtain the actual label so probably not much of a concern.)**
- Are there any liability concerns regarding the information posted (e.g., representative label is posted which consumer accesses but has adverse event based on product with a slightly different label)?
- Is the NLM DailyMed website the most appropriate place to have the data listed or is another more consumer-friendly or accessible website such as the FDA consumer page a better choice? Should or could the info be listed at two sites?



- Is there any information that companies are concerned may be released to competitors?  
(During the call it was suggested that there is probably no more concern for monograph products than for ANDA/NDA products.)

Questions (listed randomly):

- How would active and inactive ingredients be listed?
- Is there a rational reason why OTC monograph products should not be listed?
- Who is the target audience – healthcare professionals, consumers, or both? If both, is it possible for a single website to reach both groups? The consumer site would need to be user-friendly.
- What is the potential timing for posting the information?
  - If too little information is made available at the beginning, consumers may be discouraged from visiting the site if too few products are listed.
  - A contrasting opinion was that by having the information publicly available, consumers may be encouraged to seek information resulting in enhanced compliance.